

Add the following claims:

4  
3  
8. A therapeutic composition comprising an amount of (-)-benzhydrysulfinylacetamide in combination with a physiologically acceptable excipient effective to serve as an arousing agent.

5  
9. A therapeutic composition comprising an amount effective as a central nervous system stimulant of (-)-benzhydrysulfinylacetamide in combination with a physiologically acceptable excipient.

6  
10. A pharmaceutical composition useful in therapy as a central nervous system stimulant consisting essentially of (-)-benzhydrysulfinylacetamide in combination with a physiologically acceptable medium.

Cancel claims 2 and 5 to 7 without prejudice.

R E M A R K S

Claims 3 and 4 have been amended in the manner set forth herein to more particularly define applicant's invention and to overcome the objections thereof by the Examiner. New claims 8 to 10 have been added to provide patent protection for embodiments of the invention which are disclosed in the application as filed. Claim 2 has been rewritten as new claims 8 and 9 and claims 5 to 7 have been cancelled without prejudice in the light of the Examiner's requirement for restriction.

At the outset applicant acknowledges the Examiner's requirement for restriction between the invention of Group I, to wit, claims 1 to 4, and the invention of Group II, to wit, claims 5 to 7.

In view of such requirement for restriction by the Examiner, applicant elects, without traverse, to prosecute the invention of Group I in the present application. Non-elected claims 5 to 7, which are drawn to a method of preparing the compound of the invention have been cancelled without prejudice. However, applicant reserves the right to file a divisional application with claims covering the non-elected invention in due course.

In view of the amendment herein of the title of the invention and of the abstract, it is believed that the objections thereto by the Examiner have been overcome.

Claims 2 to 7 have been rejected under 35 U.S.C. 112, first and second paragraphs on the grounds that the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

In view of the amendments herein to claims 3 and 4, rewriting of claim 2 as claims 8 and 9 and cancellation of claims 5 to 7, it is believed that all of the objections of the Examiner have been overcome, and the rejection of the claims should, thus, be withdrawn. It is submitted that the claims in the present form would be clear and readily understood, both as to the meaning and boundaries thereof, by one having ordinary skill in the art. The teaching of the specification as a whole, which describes the invention in great detail and includes numerous demonstrations would make clear to one having ordinary skill in the art the applicant's inventive compositions and the method of treatment of patients for hypersomnia and Alzheimer's disease. The boundaries of the treatment and compositions for particular patients could be readily determined without the need for undue amounts of experimentation and thus further meet the requirements of 35 U.S.C. 112.

Claims 1 and 2 have been rejected under 35 U.S.C. 103 as being unpatentable over Lafon I or II. This rejection is respectfully traversed.

The Examiner maintains that "the references disclose the racemate of the claimed levorotatory compound, therapeutic compositions thereof and useful in treatment

awakening disorders and of confusion especially in the elderly. The claimed optical isomer would be obvious from the racemate containing it in the absence of any unobvious properties. It would be quite obvious to use the particular optical isomer which had the greater activity."

Lafon I, U.S. Patent 4,177,290, discloses, as noted by the Examiner, the racemate compound (+)-benz-hydrylsulfinylacetamide which is coded as CRL 40 476. The reference (see column 7, lines 18-19) shows that "CRL 40 476 did not alter the length", that is, duration "of the barbituate induced sleep".

Lafon II, EPA 0 097 071, is concerned with derivatives of the racemate which comprises at least one substituent either on one of the two phenyl rings or on the nitrogen atom. Said substituted compounds provoke a significant decrease in the sleep duration induced by pentobarbital, as explained on page 4, lines 1-10 and table IV of the publication. It should be noted that the translated abstract of EP-A - 0 097 071 is incorrect when it indicates that the comparison product (i.e. CRL 40 476) increases the duration of sleep since such an increase is not supported by the comments of the above noted page 4.


The levorotatory isomer which is coded as CRL 40 492, differs from the racemate CRL 40 476 and from the dextrorotatory isomer CRL 40 493, in the sense that its metabolism is different, as shown by the comparative assay given in the disclosure, (see chapter "PHARMACOKINETIC STUDY" from page 8 line 26 to page 10, line 33 and table II of page 12). Such comparative assays surprisingly show that isomer CRL 40 982 of the invention exhibits an unobvious bioavailability when administering in vivo, in comparison to the racemate CRL 40 476 and dextro isomer CRL 40 983. In view of these results, it would not be necessary to determine whether or not CRL 40 982 provokes an increase or a decrease in the duration of the pentobarbital induced sleep.

Moreover, the use of the isomer of the invention CRL 40 982 in the treatment of Alzheimer's disease is neither disclosed nor even remotely suggested by Lafon I or Lafon II, taken alone or in combination. Accordingly, it is submitted that claims 1 and 2 (now 8 and 9) are patentably distinct over the references, and the rejection thereof should be withdrawn.

It is respectfully submitted that applicant has made a significant invention of which there is no counterpart in any of the references of record. The claims

as presented herein carefully define the present invention,  
are proper in form and are fully supported by the  
application as filed. Reconsideration of the specification  
and claims in their present form, and early and favorable  
action is, accordingly courteously solicited.

Respectfully submitted,

By   
Franklyn Schoenberg  
Attorney for Applicant  
Registration No. 22208

Dated: July 5, 1988

KUHN AND MULLER  
1412 Broadway  
New York, NY 10018  
(212) 221-0864